



AMIODARONE

Description

Amiodarone (am-ee-OH-da-rone) belongs to the group of medicines known as antiarrhythmics. It is used to correct life-threatening heartbeat problems called ventricular arrhythmias in adults when other treatments did not work or were not tolerated.

Amiodarone produces its helpful effects by slowing nerve impulses in the heart and acting directly on the heart tissues.

This medicine is available only with your doctor's prescription, in the following dosage forms:

Parenteral

- Injection (U.S. and Canada)

Before Using This Medicine

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For amiodarone, the following should be considered:

Allergies—Tell your doctor if you have ever had any unusual or allergic reaction to amiodarone or iodine or any of the other ingredients in the tablet. Also tell your health care professional if you are allergic to any other substances, such as foods, preservatives, or dyes.

Pregnancy—Amiodarone has been shown to cause thyroid problems in babies whose mothers took amiodarone when pregnant and there is concern that amiodarone could cause slow heartbeat in the newborn. In addition, amiodarone can stay in your body for months after you have stopped taking it. However, this medicine may be needed in serious situations that threaten the mother's life. Be sure you have discussed this with your doctor before taking this medicine.

Breast-feeding—Amiodarone passes into the breast milk and has been shown to cause unwanted effects. In addition, amiodarone can stay in your body for months after you have stopped taking it. It may be necessary for you to stop breast-feeding during treatment. Be sure you have discussed the risks and benefits of the medicine with your doctor.

Children—Amiodarone can cause serious side effects in any patient. Therefore, it is especially important that you discuss with the child's doctor the good that this medicine may do as well as the risks of using it.

Older adults—Elderly patients may be more likely to get thyroid problems with this medicine. Also, difficulty in walking and numbness, tingling, trembling, or weakness in hands or feet are more likely to occur in the elderly.

Other medicines—Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. *Tell your health care professional if you are taking any other prescription or nonprescription (over-the-counter [OTC]) medicines, herbal supplements including St. John's Wort, or vitamin supplements.* When you are taking amiodarone, it is especially important that your health care professional know if you are taking any of the following:

- Anticoagulants (blood thinners) or
- Other heart medicine or
- Phenytoin (e.g., Dilantin)—Effects may be increased
- Azoles (e.g., fluconazole [Diflucan], miconazole injection [Monistat IV], ketoconazole [Nizoral], itraconazole [Sporanox], voriconazole [Vfend]) or
- Fluoroquinolones (ciprofloxacin [e.g., Cipro], enoxacin [e.g., Penetrex], grepafloxacin [e.g., Raxar], levofloxacin [e.g., Levaquin], lomefloxacin [e.g., Maxaquin], norfloxacin [e.g., Noroxin], ofloxacin [e.g., Floxin], sparfloxacin [e.g., Zagam]) or
- Macrolide antibiotics (azithromycin [e.g., Zithromax], clarithromycin [e.g., Biaxin], erythromycin [e.g., Ery-Tab])—Heart problems can result when any of these medicines are given together with amiodarone.

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- Fentanyl (e.g., Duragesic)—Using this medicine together with amiodarone may cause low blood pressure, slowed heart rate, and other heart problems.
- Simvastatin (e.g., Zocor)—May cause adverse effects with the nervous system and muscles

Other medical problems—The presence of other medical problems may affect the use of amiodarone. Make sure you tell your doctor if you have any other medical problems, especially:

- Heartbeat problems—Amiodarone may make these problems worse.
- Hepatitis, acute—Risk of adverse effects is increased.
- Liver disease—Effects of amiodarone may be increased because of slower removal from the body
- Lung problems—Unwanted effects of amiodarone on the lungs may be worse
- Thyroid problems—Risk of overactive or underactive thyroid is increased

Proper Use of This Medicine

Take amiodarone exactly as directed by your doctor even though you may feel well. Do not take more medicine than ordered and do not miss any doses.

Oral amiodarone should not be taken with grapefruit juice or other grapefruit products because these may increase the concentrations of amiodarone in the body.

Read the medication guide for amiodarone tablets before you begin taking them and each time you get a refill. There may be new information. This does not take the place of talking with your doctor about your treatment.

Your doctor will tell you to take amiodarone tablets with or without meals. Make sure you take amiodarone tablets the same way each time.

Dosing—

The dose of amiodarone will be different for different patients. *Follow your doctor's orders or the directions on the label.* The following information includes only the average doses of amiodarone. *If your dose is different, do not change it unless your doctor tells you to do so:*

- For oral dosage form (tablets):
 - For treatment of *ventricular arrhythmias*:
 - Adults—At first, 800 to 1600 milligrams (mg) per day taken in divided doses. Then, 600 to 800 mg per day for one month. Then, 400 mg per day.
 - Children—Dose is based on body weight and must be determined by your doctor. The dose for the first ten days is usually 10 mg per kilogram (4.55 mg per pound) of body weight per day. Then, the dose is decreased to 5 mg per kilogram (2.27 mg per pound) of body weight per day. After several weeks, the dose is then decreased to 2.5 mg per kilogram (1.14 mg per pound) of body weight per day.
 - For *injection* dosage form:
 - For treatment of *ventricular arrhythmias*
 - Adults—At first, the dose is 150 mg injected into a vein for ten minutes, followed by a dose of 360 mg injected into a vein for six hours, followed by a dose of 540 mg injected into a vein for eighteen hours. After the first twenty-four hours of therapy, the dose is 720 mg injected into a vein every twenty-four hours; this dose may be continued for as long as three weeks.
 - Children—Use is not recommended.

Missed dose—

If you miss a dose of this medicine, do not take the missed dose at all and do not double the next one. Instead, go back to your regular dosing schedule. If you miss two or more doses in a row, check with your doctor.

Storage—

To store this medicine:

- Keep out of the reach of children.
- Store away from heat and direct light.
- Do not store in the bathroom, near the kitchen sink, or in other damp places. Heat or moisture may cause the medicine to break down.

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- Do not keep outdated medicine or medicine no longer needed. Be sure that any discarded medicine is out of the reach of children.

Precautions While Using This Medicine

It is important that your doctor check your progress at regular visits to make sure the medicine is working properly. This will allow for changes to be made in the amount of medicine you are taking, if necessary. It is important that you have regular eye exams before and during treatment with this medicine.

Your doctor may want you to carry a medical identification card or bracelet stating that you are taking this medicine.

Before having any kind of surgery (including dental surgery) or emergency treatment, tell the medical doctor or dentist in charge that you are taking this medicine.

Amiodarone increases the sensitivity of your skin to sunlight; too much exposure could cause a serious sunburn. Your skin may continue to be sensitive to sunlight for several months after treatment with this medicine is stopped. A sunburn can occur even through window glass or thin cotton clothing. If you must go out in the sunlight, *cover your skin and wear a wide-brimmed hat. A product applied to the skin to prevent sunburn should also be used. In case of a severe sunburn, check with your doctor.*

After you have taken this medicine for a long time, it may cause a blue-gray color to appear on your skin, especially in areas exposed to the sun, such as your face, neck, and arms. This color will usually fade after treatment with amiodarone has ended, although it may take several months. However, check with your doctor if this effect occurs.

Check with your doctor if you notice any changes in your vision, such as a decrease in peripheral vision or in the clarity of the objects that you see, blurred vision, see halos, or your eyes become sensitive to light.

Side Effects of This Medicine

Side Effects of This Medicine

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention. Also, some side effects may not appear until several weeks or months, or even years, after you start taking amiodarone.

Check with your doctor immediately if any of the following side effects occur:

- *More common*
 - Cough; painful breathing; shortness of breath

Check with your doctor as soon as possible if any of the following side effects occur:

- *More common*
 - Dizziness, lightheadedness, or fainting; fever (slight); numbness or tingling in fingers or toes; sensitivity of skin to sunlight; trembling or shaking of hands; trouble in walking; unusual and uncontrolled movements of the body; weakness of arms or legs
- *Less common*
 - Blue-gray coloring of skin on face, neck, and arms; blurred vision or blue-green halos seen around objects; coldness; dry eyes; dry, puffy skin; fast or irregular heartbeat; nervousness; pain and swelling in scrotum ; sensitivity of eyes to light; sensitivity to heat; slow heartbeat; sweating; swelling of feet or lower legs; trouble in sleeping; unusual tiredness; weight gain or loss
- *Rare*
 - Skin rash; yellow eyes or skin
- *Frequency not determined*
 - Abdominal or stomach pain; agitation ; back, leg, or stomach pains; bleeding gums; blistering, peeling, loosening of skin; bloating; blood in urine; bloody, black, or tarry stools; blue lips, fingernails, or skin; blurred or double vision; chest pain; chills; clay-colored stools; coma; confusion; confusion as to time, place, or person; coughing or spitting up blood; cracks in the skin; dark urine; decreased urine output; depression; diarrhea; difficult or labored breathing; difficult urination ; dry cough; eye pain; fast heartbeat; fatigue; general body swelling; hallucinations ; high fever; holding false beliefs that cannot be change by fact; hostility ; inability to have or keep an erection; indigestion; irregular, fast or slow, or shallow breathing; irritability; itching; joint or muscle pain; large, hive-like swelling on face, eyelids, lips, tongue, throat, hands,

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legs, feet, sex organs; lethargy; loss in sexual ability, desire, drive, or performance; loss of heat from the body; lower back or side pain; mood or mental change; muscle cramps or spasms; muscle pain or stiffness; muscle twitching; no breathing; noisy breathing; nosebleeds; pain in abdomen, groin, or scrotum; pain or burning with urination; pains in stomach, side, or abdomen, possibly radiating to the back; pale skin; pinpoint red spots on skin ; rapid weight gain; rash ; red irritated eyes; red skin lesions, often with a purple center; red, swollen skin; scaly skin; seeing, hearing, or feeling things that are not there; seizures ; severe headache; sneezing ; sore throat; sores, ulcers, or white spots on lips or in mouth; stupor; swelling of face, ankles, or hands; swelling of scrotum; swollen or painful glands; tightness in chest; troubled breathing; unpleasant breath odor; unusual bleeding or bruising ; unusual excitement, nervousness, or restlessness ; unusual tiredness or weakness; vomiting of blood; weakness; wheezing

Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor if any of the following side effects continue or are bothersome:

- *More common*
 - Constipation; headache; loss of appetite; nausea and vomiting
- *Less common*
 - Bitter or metallic taste; decreased sexual ability in males; decrease in sexual interest ; dizziness; flushing of face

After you stop using this medicine, your body may need time to adjust. The length of time this takes depends on the amount of medicine you were using and how long you used it. During this period of time check with your doctor if you notice any of the following side effects:

- Cough; fever (slight); painful breathing; shortness of breath

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor.

**Brand Names
In the U.S.—**

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| • Cordarone | • Cordarone I.V. |
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In Canada—

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| • Cordarone | • pms-Amiodarone |
| • Cordarone Intravenous | |

Category

- Antiarrhythmic

END OF INFORMATION – NOTHING FOLLOWS